

II. REMARKS:

A. Status of the Claims

Claims 1-22 were originally filed with the case. Claims 1-4 were cancelled and claims 5-8 and 14-17 were amended in a Response to Office Action filed on January 17, 2006. All claims were rejected in an Office Action mailed on November 16, 2006. Claims 5 and 14 are amended herein. Support for the amendments to claims 5 and 14 can be found in the specification, for example, at page 9, lines 7-12. Thus, claims 5-22 remain pending.

B. The Claims are Enabled

The Action first rejects claims 5-22 under 35 U.S.C. § 112, first paragraph, as lacking enablement. The Action acknowledges that the claims are enabled for a method of treating dry eye condition in a non-human mammal by administering to an eye of a non-human mammal a nucleic acid composition comprising a eukaryotic promoter operably linked to the nucleotide sequence disclosed in SEQ ID NO. 1 or 3 in an ocular drop, wherein the expression of the transgene results in treatment of the dry eye condition. The Action asserts that the art of gene therapy is unpredictable and therefore the practice of the invention would require undue experimentation. Applicants respectfully traverse.

The corneal epithelia of many mammals contain significant activities of 15-LO. The inventors have shown that the ocular surface epithelium of postmenopausal women is lacking 15-LO. 15-LO is required for the synthesis of 15(S)-HETE, which in turn stimulates the production of MUC-1 mucin. The present invention provides methods for increasing the

expression of 15-LO-1 or 15-LO-2 in the ocular surface epithelium of postmenopausal women suffering from dry eye.

The cornea has been shown to be readily accessible to gene therapy by injection of naked plasma DNA into the cornea (Stechschulte *et al.*, *Invest. Ophthalm. Vis. Sci.* 42(9):1975-1979 (2001)). It has also been shown that exogenous nucleic acid may be introduced into ocular cells by contacting ocular cells with exogenous nucleic acid under conditions that allow the ocular cell to take up the exogenous nucleic acid into the ocular cell and express it. Such conditions are described, for example, in U.S. Patent no. 6,204,251 (Cuthbertson). Cuthbertson describes general methods for effecting expression of an exogenous gene in ocular cells. Cuthbertson is incorporated by reference into the present specification.

It is submitted that the claims are enabled when read in light of the specification, including the art that is incorporated by reference into the specification. That is, the skilled artisan would reasonably expect the claimed invention to work as described.

In light of the foregoing arguments, Applicants respectfully request that the enablement rejection be withdrawn.

C. The Claims are Patentable Over Co-Pending Application No. 10/539,093

Claims 5-22 are provisionally rejection under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-22 of co-pending application no. 10/539,093. The claims of the '093 application are said to be directed to a method for treating dry eye by obtaining a

composition comprising SEQ ID NO:1 or SEQ ID NO:3 and administering the composition to a patient suffering from dry eye. Applicants respectfully traverse.

The current claims are directed to a method for increasing the expression of 15-LO or 15-LO-2 in a postmenopausal patient by contacting an ocular cell with an exogenous nucleic acid under conditions such that the nucleic acid will be taken up by the cell and expressed therein. It is submitted that the currently pending claims are not directed to the same invention as that claimed in the co-pending '093 application.

In light of the foregoing arguments, applicants respectfully request that the provisional double patenting rejection be withdrawn.

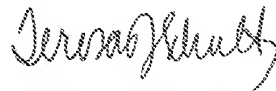
D. Conclusion

This is submitted to be a complete response to the outstanding Final Office Action. Based on the foregoing arguments, the claims are believed to be in condition for allowance; a notice of allowability is therefore respectfully requested.

In re Application of: John M. YANNI
Serial No.: 10/688,676 (Conf. #2568)
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The Examiner is invited to contact the undersigned attorney at (817) 551-4321 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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